K052637

MAR 8 2006

510(k) SUMMARY

Date Prepared: August 19, 2005

Name and Address of Submitter: TherOx, Inc.
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Contact Name : Kevin Larkin, President and CEO

Trade/ Proprietary Name: TherOx® Infusion Catheter (Model No.: INCA-1)

Classification Name: Catheter, Intravascular, Diagnostic

Device Classification: Class II per 21 CFR 870.1200

SUBSTANTIAL EQUIVALENCE STATEMENT

The TherOx® Infusion Catheter, manufactured by TherOx, Inc., is substantially equivalent to the Boston Scientific/Target Therapeutics Tracker® - 38 Infusion Catheter cleared for market under 510(k) nos. K853997 and K862117. [1] Both catheters are intended to enable delivery of diagnostic and therapeutic solutions into the peripheral and coronary vasculature when introduced percutaneously to the body through commercially available guide catheters and over commercially available guidewires. Both catheters are sterile, single lumen, end-hole catheters intended for single-use only. The substantial equivalence of the catheters is supported by physical and mechanical characteristics that are very similar and by the fact that the peripheral and coronary vessel applications for each catheter are the same.

DEVICE DESCRIPTION

The TherOx® Infusion Catheter is a sterile, single-use, 4.6 French (F) intravascular catheter with a 127 cm usable length. The catheter is comprised of three sections; 1) a distal atraumatic soft tip 2) a semi-rigid but flexible shaft; and 3) a proximal luer hub for connection of solution-delivery devices. A radiopaque band at the distal tip allows fluoroscopic visualization of the catheter's location in the vessel.

The TherOx® Infusion Catheter is packaged in standard medical product packaging and sterilized with ethylene oxide. The catheter and its packaging have been qualified for a three-year shelf life under conditions of proper storage and handling.

[1] TherOx is a registered trademark of TherOx, Inc. All other trademarks referenced are the property of their respective owners.

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INTENDED USE

The TherOx® Infusion Catheter is intended to assist in the controlled infusion of diagnostic or therapeutic solutions into the peripheral and coronary vasculature. The target vessel effective diameter is ≥ 2.0 mm. The catheter is placed by a physician using a guide catheter and over a guidewire that extends beyond the final position of the infusion catheter.

CONTRAINDICATIONS

- Do not place in a vessel with an effective diameter of < 2.0 mm.
- Not intended for pediatric or neonatal use.

TECHNOLOGY COMPARISON

The TherOx® Infusion Catheter is very similar in design and performance characteristics when compared to the Tracker® - 38 Infusion Catheter predicate device. Both catheters have a soft atraumatic tip and a flexible shaft that facilitates maneuverability within the target vessel. Both catheters have a female luer hub for attachment of solution delivery devices and a radiopaque marker band at the tip to visualize catheter location under fluoroscopy. A comparison of catheter characteristics demonstrates that both catheters meet the requirements of the ISO 10555 series of standards for intravascular catheters. Both devices are substantially equivalent relative to strength, flexibility, pressure, and flow properties.

Minor differences are enumerated in **Table 1**, below, and are explained following the table.

TABLE 1 – Summary of Catheter Differences

Characteristic	TherOx® Infusion Catheter	Tracker® - 38 Infusion Catheter
1. Outer Diameter	4.6 F (0.060 in) overall	5.3 F (0.070 in) overall 5 F (0.066 in) at tip
2. Inner Diameter	0.046 in overall 0.037 in min at marker band	0.046 in overall 0.040 in at marker band
3. Usable Length	127 cm	115 cm [1]
4. Materials	High density polyethylene (HDPE) shaft Rigid HDPE luer LDPE plasticized tip	Polypropylene/Low density polyethylene (LDPE) shaf Rigid clear thermoplastic luer LDPE plasticized tip

[1] – 117 cm as labeled which includes strain relief length

1. The TherOx® Infusion Catheter has a smaller outer diameter that allows use with smaller guide catheters.
2. The TherOx® Infusion Catheter has a slightly smaller inner diameter at the marker band but use of the recommended size guidewire is not impeded.

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3. The TherOx® Infusion Catheter has an extra 12 cm of usable length that aids the physician in securing and manipulating the catheter outside the body and that accommodates taller patients.

4. The distal tip materials for both catheters are the same but the shaft and luer hub materials are different. Despite these minor differences, adherence to critical performance attributes as specified in applicable voluntary standards has been maintained.

NON-CLINICAL TEST DATA SUMMARY

A battery of strength, flexibility, flow, and pressure tests as specified in the standards listed below was performed on both the TherOx® Infusion Catheter and the predicate Tracker® - 38 Infusion Catheter device. The tests were performed to verify comparable performance of the devices and to verify conformance to TherOx device specifications.

Test results were obtained for production samples that were sterilized twice in a validated sterilization cycle, and on samples that were sterilized twice and then thermally aged to simulate an expected shelf life. Dimensional conformance, joint strength, flexibility, pressure rating, and flow characteristics were tested on these sample groups and the test requirements were specified based on the following voluntary standard and guidance documents:

1. FDA "Guidance on Premarket Notification (510(k)) Submission for Short-Term and Long-Term Intravascular Catheters" March 1995
2. ISO 10555-1 " Sterile Single-Use Intravascular Catheters – General Requirements"
3. ISO 10555-2 " Sterile Single-Use Intravascular Catheters – Angiographic Catheters"
4. ISO 10555-3 " Sterile Single-Use Intravascular Catheters – Central Venous Catheters"

In addition, the TherOx infusion catheter satisfies the biocompatibility requirements of ISO 10993-1 and is sterilized in an ethylene oxide (EtO) sterilization cycle validated per ISO 11135. The TherOx catheter packaging was designed and tested per the requirements of ISO 11607.

All functional and performance test results met their acceptance criteria and a 3-year shelf life was established for the finished product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2006

Therox, Inc.
c/o Underwriters Laboratories, Inc.
1285 Walt Whitman Rd.
Melville, NY 11747
Attn: Mr. Casey Conry

Re: K052637
TherOx® Infusion Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO
Dated: February 22, 2006
Received: February 24, 2006

Dear Mr. Conry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vickers

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): Unknown K052637

Device Name: TherOx® Infusion Catheter

Indications for Use:

The infusion catheter is intended to assist in the controlled infusion of diagnostic or therapeutic solutions into the peripheral or coronary vasculature. The target vessel effective diameter is ≥ 2.0 mm. The catheter is placed by a physician using a guide catheter and over a guidewire that extends beyond the final position of the infusion catheter.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

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